

REMARKS

This is in response to the Office Action mailed October 22, 2002, in the above-referenced application. The rejections of record are addressed below in the order presented in the Office Action.

Claims 1-2, 4, 6-8, 10 and 12-14 are rejected under 35 USC § 112, second paragraph, as indefinite for the reasons set forth at paragraphs 1-4 on pages 2 and 3 of the Office Action. Applicants offer the following comments.

The Office requests clarification of the expression "one or more neutralized esters of one or more monoglycerides, diglycerides, or both, of one or more saturated fatty acids with citric acid." The compounds described by this expression are esters of a fatty acid and glycerol, thus the use of the terms "monoglycerides" and "diglycerides" in the claims. The resultant esters are further reacted with citric acid. The resultant compound may generally be described as an ester of a fatty acid, glycerol, and citric acid. One advantageous mixed ester as described in the application is glyceryl stearate citrate. See page 9, lines 6-9 of the present application. Applicants respectfully submit that this expression is clearly defined in the application as filed and one skilled in the art would understand the meaning of the same.

The Office also objects to the term "saturated fatty acids," arguing that the specification does not define the carbon chain length thereof. Applicants submit that one skilled in the art would understand the meaning of this term as well in view of the discussion in the application with regard to various fatty acids. For example, the Office's attention is directed to page 26, lines 19-21 of the application which defines diglycerol esters of saturated and/or unsaturated, branched and/or unbranched alkane carboxylic acids having a chain length of from 8 to 24. One skilled in the art would appreciate that the chain length described therein also applies for the esters as claimed.

The Office objects to the term "retinoic esters," arguing that the specification does not define the carbon range for the ester at page 9. Again, however, one skilled in the art would understand the meaning of this term based upon a reading of the application as a whole. In this regard, the Office's attention is directed to page 8, lines 11 and 12, which define the carbon

range for retinol esters, which range is also applicable for the retinoic acid esters as recited in the claims.

Claims 2 and 8 are amended as suggested by the Examiner. This amendment does not affect the scope of protection afforded to Applicants, including any protection available under the doctrine of equivalents. The amendment does not narrow the claims but merely restates what is already presented in the claim. In addition, Claim 6 is amended as suggested by the Examiner to delete the phrase "and the like." Again, this amendment does not affect the scope of protection afforded to Applicants because the amendment does not narrow the claim recitations.

In view of the foregoing clarifying comments and amendments, Applicants respectfully request withdrawal of this rejection.

Claims 1-14 are rejected under 35 USC § 103 as unpatentable over the combination of U.S. Patent No. 6,419,946 and U.S. Patent No. 5,985,296. Applicants respectfully traverse this rejection.

The '946 patent is directed to nanoemulsions which include a mixed ester of a fatty acid, a carboxylic acid and a glycerol as a surfactant. The '946 patent does not suggest the addition of retinol or its derivatives, much less retinol or its derivatives stabilized with a cyclodextrin, to the nanoemulsions. The '946 patent certainly does not teach or suggest that the claimed combination can exhibit a synergistic effect in increasing the stability of such compounds against chemical degradation.

The Office argues that the '946 patent teaches that the emulsions are "stable on storage" (column 1, line 19). This, however, refers to the nanoemulsion per se and not to active ingredients added thereto as in the present application. The stability appears to be an important factor, as the '946 patent distinguishes the nanoemulsions described therein from microemulsions, such as used in the present invention. Column 1, lines 36-54. To this end, the '946 patent requires that the nanoemulsions are devoid of any surfactant other than the mixed esters, whereas the present compositions can include more than one surfactant.

The '296 patent does not overcome the deficiencies of the '946 patent. The '296 patent is directed to complexes of γ -cyclodextrin and retinol or retinol derivatives, stated to stabilize retinol or retinol derivatives. The '296 patent does not, however, teach or suggest specific types

of surfactants for use with the complexes, much teach or suggest the use of the ester compounds as claimed.

The '296 patent certainly does not recognize the synergistic stabilizing effect of the claimed combination. Indeed, when read in its entirety for all that it fairly suggests, the '296 patent teaches away from the use of additional stabilizing agents. See column 2, line 61 through column 3, line 7.

In support of the synergistic effect provided by the claimed composition, submitted concurrently herewith is a Rule 132 Declaration by Thomas Raschke, one of the named co-inventors in the present application. Mr. Raschke compared the stability of a retinoid in a composition including a glyceride and saturated fatty acid ester, partially neutralized with citric acid, as an emulsifier, to the stability of the same retinoid in a composition including a different emulsifier. Specifically, Mr. Raschke compared the stability of a retinol- γ -cyclodextrin complex in a composition that includes glycerol stearate citrate as an emulsifier with the stability of the same retinol- γ -cyclodextrin complex in a composition that includes glycerol stearate as an emulsifier.

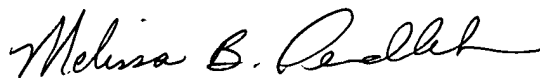
The results are set forth in the table on page 4 of the 132 Declaration. The data demonstrates the significantly improved performance of the claimed composition as compared to a composition without the same surfactant. After three months, the retinol-cyclodextrin complex of the claimed composition exhibits an activity almost twice that of the same complex without the same surfactant.

In summary, the cited patents do not teach or suggest combining the components as claimed, much less that such a combination would improve the stability of retinol or its derivatives. Certainly neither the '946 nor the '296 patents suggests, singly or in combination, the synergistic effect with regard to retinol stability demonstrated by Applicants in the Rule 132 Declaration. Further, the '296 patent teaches away from the invention because it teaches away from the use of additional retinol stabilizers. In view of the foregoing, the Office requires an improper hindsight analysis to conclude that the claimed invention is obvious. Accordingly, Applicants respectfully request withdrawal of this rejection and indication of the patentability of the claimed invention.

The rejections of record having been addressed in full in the foregoing, Applicants respectfully submit that this application is now in condition for allowance, which action is respectfully requested. Should the Examiner have any questions regarding the foregoing, it is respectfully requested that the Examiner contact the undersigned to expedite examination of this matter.

It is not believed that extensions of time or fees for net addition of claims are required, beyond those that may otherwise be provided for in documents accompanying this paper. However, in the event that additional extensions of time are necessary to allow consideration of this paper, such extensions are hereby petitioned under 37 CFR § 1.136(a), and any fee required therefore (including fees for net addition of claims) is hereby authorized to be charged to Deposit Account No. 16-0605.

Respectfully submitted,

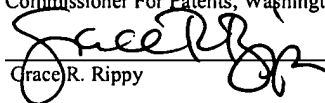


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I hereby certify that this paper or fee is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.10 on the date indicated above and is addressed to: Commissioner For Patents, Washington, DC 20231.


Grace R. Rippy

Version with Markings to Show Changes Made:

2. (Amended) The composition of Claim 1, wherein the one or more retinoids is selected from retinol [and], retinol esters [thereof], retinal, [and] retinoic acid and retinoic acid esters [thereof].

6. (Amended) A composition useful for the treatment or prophylaxis of skin against damage resulting from aging[,] and exposure to oxidative influences, [and the like,] the composition comprising:

- (a) glyceryl stearate citrate; and
- (b) a retinol- γ -cyclodextrin complex.

8. (Amended) The emulsion of Claim 7, wherein the one or more retinoids is selected from retinol [and], retinol esters [thereof], retinal, [and] retinoic acid and retinoic acid esters [thereof].